510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date: November 20th, 2013

Submitter:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact:
Helen Peng
Regulatory Affairs Leader, RAC
GE Medical Systems, LLC
Tel: 262-424-8222
e-mail: hong.peng@ge.com

Secondary Contact:
John Jaeckle
Chief Regulatory Affairs Strategist
GE Medical Systems, LLC
Tel: 262-424-9547
e-mail: john.jaeckle@ge.com

PRODUCT IDENTIFICATION

Device Trade Name: Revolution CT

Common/Usual Name: Computed Tomography X-ray System

Classification Name: Computed Tomography X-ray System per 21CFR892.1750

Product Code: 90-JAK

Manufacturer / Design Location:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Manufacturing Location(s):
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Distributor:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices:

The Revolution CT is a new CT device built upon the existing technologies of the predicate device Discovery CT750 HD (K120833). It is of comparable type and substantially equivalent to its predicate device Discovery CT750 HD and GE's other currently marketed Computed Tomography X-ray Systems that comply with the same standards. In addition, the system has the same intended use as that of the predicate device. The proposed device's indications for use have been revised to match the system capabilities as substantiated in the engineering and clinical testing provided. The system is labeled as the Revolution CT.

Predicate Device:

Discovery CT750 HD- K120833

DEVICE DESCRIPTION

The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry rotates at up to 0.28 seconds per rotation, and can acquire up to 512 slices of image data per rotation with a maximum total coverage of 160 mm in the z direction. The gantry however is designed to be able to rotate at 0.20 second per rotation. The system can be operated in Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisition modes.

The Revolution CT system is a powerful Volume High Definition CT scanner that is designed to provide best-in-class technologies for whole organ coverage, high image quality and responsible dose performance with the following characteristics:

- 160 mm detector coverage
- 140ms temporal resolution (0.28s rot. Speed) combined with intelligent motion correction with SnapShot Freeze for excellent cardiac imaging at any heart rate.
- 0.23 mm spatial resolution
- A wide bore (80-cm bore size) to image all patients allowing better patient positioning & access.
- The next-generation of iterative reconstruction technology, ASiR-V, designed to deliver ultra-low noise levels, improved low contrast detectability and may enable a reduction in dose for all clinical applications

Built upon the existing technologies the Revolution system is designed to use less radiation dose than the previous generation product while maintaining the same diagnostic level of image quality. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Gemstone spectral imaging and 0.2s rotation speed.

The Revolution CT is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same intended for use as the predicate device. Materials and construction are equivalent to our existing marketed products, which are compliant with AAMI/ES 60601-1, IEC 60601-1(3rd ed) and associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. It has been developed under the same GE quality system and has successfully completed design controls activities, including risk management, verification, and validation.

Intended Use

The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use:

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy..

Technology:

The Revolution CT is built on the existing technologies of the predicate device Discovery CT750 HD. The vast majority of the software features and functions are common between the two products. The software user interface has been redesigned to provide more simplified workflow and user experience. Hardware components including the imaging chain however have been upgraded to support the new and improved capabilities.

The most notable changes in the imaging chain as compared to the predicate device Discovery CT750 HD is described below.

The Revolution CT system features the new "Gemstone Clarity" detector consisting of 256 rows at 0.625mm row thickness and a full 160mm z-coverage, the redesigned gantry with a 80cm bore and improved iterative reconstruction technology, allowing the system to deliver excellent image quality at full 160mm coverage to enable whole organ imaging.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems.

To house the wide Gemstone Clarity detector, the Revolution gantry has been redesigned with high specifications of strength and rigidity that support fast rotation speeds for acquisitions with high temporal resolution, while providing an 80cm bore opening to accommodate patients with positioning flexibility and comfort. With an improved center mount design that balances the mechanical forces generated by the rotating components, the gantry and detector assembly is capable of supporting accelerations that ensures reliable operation at today's 0.28 seconds per rotation, and can be extended to support imaging at 0.20 seconds per rotation in the future.

On the rotating gantry, the new Performix HDw tube tailored for the wide angle geometry generates the X-ray beam for patient imaging.

To address the challenges of the wide cone-beam geometry of the new scanner, a new advanced image reconstruction algorithm called Volumetric High Definition (VHD) has been designed specifically to reduce cone-beam artifacts and maintain CT number uniformity.

The image reconstruction engine further includes ASiR-V, the next generation of GE's ASiR iterative recon technology for noise reduction and dose management. Finally, GE's SnapShot Freeze technology is supported on all cardiac acquisitions to improve the temporal properties of the reconstructed images when visualizing the coronaries.

Despite the changes described above, the control mechanism, operating principle, energy type, and intended use have not changed from the predicate device Discovery CT750 HD.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (AAMI/ES and IEC60601-1 Ed.3 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

Determination of Substantial Equivalence:

The Revolution CT has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. The device has successfully completed all testing per our quality system as well as comparison testing to the predicate device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Revolution CT system is of comparable type and substantially equivalent to our currently marketed system Discovery CT750 HD.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (non-Clinical testing) and clinical performance testing was performed to provide the requisite data to substantiate performance claims, the revised indications, and ultimately substantial equivalence.

Non-Clinical Testing

The performance evaluation testing used a variety of test methods, phantoms, and clinical datasets. Various mathematical, physics and statistical analysis were performed to demonstrate that each performance specification was successfully verified and substantiated. The areas additionally evaluated for the non-clinical testing included cardiac, cardiovascular, and thoracic imaging; temporal resolution, dose performance, and image quality. The image quality evaluation included evaluation for artifacts, scatter, spatial resolution, and low contrast detectability. For the LCD evaluation, a model observer study was used along with the MITA LCD phantom. Acceptance testing per IEC 61223-3-5 was also conducted.

Clinical Testing

Sample clinical data was collected from 49 subjects at one site in the US with the approval of appropriate ethics committee and in accordance with 21 CFR Parts 812, 50 and 56, as well as GE Healthcare's quality system's procedures for such evaluations.

The intent of the protocol was to obtain a sample set of clinical images across different patient populations, clinical scenarios, and scanning protocols/techniques. Patients were selected for potential recruitment to meet these needs. Any patient who met these criteria stated in the Protocol and who voluntarily signed the Informed Consent Form was recruited.

This sample image data was representative of a wide range of anatomical coverage and patient indications and was categorized into the following types of scans:

- Cardiac – Coronary CTA, Stress/Rest Perfusion, Cardiac Function, Calcium Burden, Gated Chest (Triple Rule Out), TAVI
- Body & Extremity - Abd/Pelvis, Chest, Ankle, Shoulder, Knee, Spine
- Neuro – Sinus, General Brain, Contrast Enhanced Brain, Neuroangiography, Neuro Perfusion, Neuro 4D CTA

The images were evaluated by multiple readers who are qualified radiologists at different institutions in the United States of America for clinical acceptance and image quality using a 5 point Likert scale.

The results of this clinical assessment demonstrate the acceptable diagnostic imaging performance of the GE Healthcare Revolution CT scanner.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the Revolution CT is as safe and effective, and performs in a substantially equivalent manner to the predicate device Discovery CT750 HD (K120833).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems, LLC
% Ms. Helen Peng
Regulatory Affairs Manager
3000 North Grandview Blvd.
WAUKESHA WI 53188

April 11, 2014

Re: K133705
Trade/Device Name: Revolution CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 10, 2014
Received: March 11, 2014

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133705

Device Name
Revolution CT

Indications for Use *(Describe)*

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara